UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, *Plaintiff*, v. DONALD J. TRUMP, *et al.*, *Defendants*.	:	Case No. 2:17-cv-04540-WB

***AMICI CURIAE* BRIEF OF MASSACHUSETTS, CALIFORNIA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, ILLINOIS, IOWA, MAINE, MARYLAND, MINNESOTA, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, RHODE ISLAND, VERMONT, VIRGINIA, AND WASHINGTON IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

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Date: November 27, 2017

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INTEREST OF AMICI STATES

The *Amici* States of Massachusetts, California, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, and Washington have a compelling interest in protecting the health and well-being of their residents and the economic security of their families. To promote these interests, the States are committed to ensuring a strong and robust regulatory regime that makes contraception as widely available and affordable as possible. Access to contraception advances educational opportunity, workplace equality, and financial empowerment for women, improves the health of women and children, and reduces health-care related costs for States. Many States have laws requiring health insurance plans to cover FDA-approved contraception, a mandate mirrored under federal law, including for those self-insured plans not subject to state regulation. Since the federal government plays a central role in the regulation and oversight of the health care system, the *Amici* States have a strong interest in ensuring that federal agencies develop rules that further these health and equality objectives and promote policies enabling States to avoid immediate and downstream costs.

The *Amici* States are also deeply committed to the religious freedom of their residents. Some, in fact, have state statutes and constitutional provisions that extend protection beyond the requirements of federal law and the United States Constitution. But the *Amici* States also recognize the importance of guarding against overbroad rules and regulations that allow one group to impose their religious views on another, especially when doing so comes at the expense of other compelling interests, such as gender equality and the health of women and children.

In addition, the *Amici* States have a strong interest in a fair and transparent federal regulatory process that affords States the opportunity to provide substantive comments on the

consequences of a proposed rule. The *Amici* States depend on federal agencies to follow proper rulemaking procedures designed to ensure consideration of a broad array of interests, including those of state and local governments, before making important, and often complex, regulatory decisions. Regulatory changes that do not comport with the proper notice and comment requirements undercut public trust in the process, the new policy, and the agencies themselves.

SUMMARY OF ARGUMENT

Through this lawsuit, the Commonwealth of Pennsylvania seeks to protect itself, other States, and women across the country from the harms that will result from Defendants' attempt to nullify provisions of the Patient Protection and Affordable Care Act ("ACA") that guarantee women equal access to preventive medical care—specifically contraceptive care and services. On October 6, 2017, Defendants issued two Interim Final Rules (the "Rules") authorizing employers with religious or moral objections to contraception to block employees and their dependents from receiving health insurance coverage for contraceptive care and services.

As set forth in *Part I*, the States have suffered, and continue to suffer, harm as a result of the Rules. A wealth of research demonstrates the critical importance of contraceptive coverage for the health of women and children as well as the economic security of women and their families. By creating broad new exemptions from the ACA's contraceptive mandate, the Rules leave the States to assume additional costs related to contraception and services associated with unintended pregnancies. The Rules underestimate the foreseeable usage of the exemptions and overstate the ability of limited state-funded sources to fill critical gaps. In addition, the Rules' procedural failures and constitutional infirmities create legally cognizable harm to the States.

Part II explains that the Rules suffer from numerous legal flaws and cannot withstand judicial review because they: (i) cannot be reconciled with the ACA's requirement that regulated

employer-sponsored group health plans provide women with coverage for preventative care services; (ii) reflect a substantial departure from prior agency reasoning and determinations without adequate justification; (iii) amount to an endorsement of religion in violation of the Establishment Clause; (iv) discriminate against women in violation of the Equal Protection guarantee implicit in the Fifth Amendment; and (v) were issued without the required notice and comment rulemaking process, in violation of the Administrative Procedure Act ("APA").

The *Amici* States support Pennsylvania's request to enjoin implementation of, and to invalidate, the Rules so that no individual or family across the country is denied access to critical health care coverage, and so that the States are not forced to bear the resulting costs.

ARGUMENT

I. STATES ACROSS THE COUNTRY HAVE AND WILL CONTINUE TO SUFFER HARM AS A RESULT OF THE RULES

Defendants' unlawful attempt to nullify provisions of the ACA that guarantee women equal access to preventive medical care have caused—and continue to cause—irreparable harm to the States and their residents. The Rules jeopardize women's health and impose significant and irreparable proprietary and societal harms upon the States. In addition, Defendants' promulgation of the Rules in violation of the Establishment Clause and the procedural requirements of the APA have caused irreparable non-economic injuries to the States. Without a preliminary injunction, the harms caused by the Rules will only become more severe.

A. Widespread Availability of No-Cost Contraception Is Critical to the Economies and Public Health of the States

More than 28 million women between the ages of 15 and 45 reside in the *Amici* States. Many of them rely on contraception. Contraception affects nearly every aspect of a woman's adult life, including her health, the health of her family, and her ability to control her own

economic path. Overwhelming empirical evidence shows that, in turn, the economy and public health of States benefit significantly when contraceptive choices are made widely available at the lowest possible cost. For those reasons and more, the *Amici* States have made a commitment to improving access to contraceptive care and services through state laws as well as programmatic development and funding. But States alone cannot guarantee access. The ACA's contraceptive mandate has closed a critical gap, given the significant role that employer-sponsored insurance plays in the marketplace. The Rules significantly erode access to no-cost contraception.

1. Economic and Public Health Data Clearly Demonstrate the Benefits of Access to Contraceptive Coverage for Women

Women who can plan their pregnancies have more control over their bodies and major life choices, including if and how they pursue educational and job opportunities. For example, studies show that access to affordable contraception makes women as much as 20% more likely to pursue higher education.[1] The Joint Economic Committee found that, for women who decide to join the workforce, contraception access also helps to narrow the gender and family wage gaps. Joint Economic Committee, *The Economic Benefits of Access to Family Planning* (2015). The ability of women to plan their pregnancies has also bolstered their lifetime earnings.[2] *Id.*

Access to contraception also reduces negative health consequences for women and their children. A majority of women use contraception at least in part as birth control, and women and their children experience medical benefits when women are able to plan the timing of their

[1] Adam Sonfield et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, Guttmacher Institute, at 7, 11-12 (Mar. 2013), https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

[2] Enhancing the earning potential for women is particularly crucial given that 40% of all households with children under the age of 18 include mothers who are either the sole or primary source of income for the family. Pew Research Center, *Breadwinner Moms: Mothers are the Sole or Primary Provider in Four-in-Ten Households with Children*; *Public Conflicted about the Growing Trend*, at 1 (2013), *http://www.pewsocialtrends.org/2013/05/29/breadwinner-moms/*.

pregnancies.[3] Pregnancy timing reduces adverse pregnancy outcomes even when the mother is healthy.[4] Women with unintended pregnancies are more likely than women with planned pregnancies to receive late or no prenatal care. Pregnancies that occur within 18 months of a prior pregnancy are at higher risk of adverse outcomes like low birth weight and prematurity.[5]

The health benefits associated with contraception extend beyond those related to birth control. Oral contraceptives treat menstrual disorders and pelvic pain. Long-term use of oral contraceptives has been shown to reduce the risk of certain cancers and benign breast diseases, as well as protect against pelvic inflammatory disease.[6] In fact, nearly 15% of the over 11 million women who take oral contraceptives do so *solely* for medical reasons unrelated to birth control, and over half do so in part for such reasons.[7]

2. The Economic and Public Health Benefits of Contraception Are Maximized through No-Cost Access

The economic and public health benefits associated with family planning are best accomplished by expanding contraceptive options for women. Women with limited options are more likely to experience side effects from or otherwise be dissatisfied with their methods of contraception and are thus less likely to use contraception consistently and more likely to experience unintended pregnancy. [8] When cost is not a barrier, women increasingly choose more

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[3] R. Jones, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, Guttmacher Institute (Nov. 2011), https://www.guttmacher.org/sites/default/files/report_pdf/beyond-birth-control.pdf.

[4] Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps, at 103 (2011).

[5] M. Kavanaugh and R. Anderson, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers*, Guttmacher Institute (July 2013), https://www.guttmacher.org/sites/default/files/report_pdf/health-benefits.pdf.

[6] Institute of Medicine, Clinical Preventive Services for Women, *supra* n.4, at 107.

[7] R. Jones, *Beyond Birth Control*, *supra* n.3, at 3.

[8] Guttmacher Institute, *Improving Contraceptive Use in the United States*, at 4-5 (May 2008), https://www.guttmacher.org/sites/default/files/report_pdf/improvingcontraceptiveuse_0.pdf.

effective and reliable methods of contraception. Since the ACA's contraceptive mandate went into effect, women have increasingly chosen IUDs and oral contraceptives.[9]

Absent coverage, many methods of contraception are prohibitively expensive for a large portion of the population. Long-acting reversible contraceptives such as IUDs, which are among the most effective methods of contraception, have upfront costs in excess of $1,000.[10] To put this in perspective, the cost of an IUD is nearly equal to a month's salary for a full-time worker earning the federal minimum wage. Even less expensive methods of contraception cost about $50 a month (or $600 a year) if not covered by insurance. 82 Fed. Reg. 47,792, 47,821, and 47,858 (Oct. 13, 2017). About one-third of uninsured people and lower-income people report that they would be unable to pay for an unexpected $500 medical bill.[11] In fact, research shows that even "minor" obstacles deter use of contraception. At least one study has shown that copays as low as $6 lead to higher levels of inconsistent use and the increased likelihood of pregnancy.[12]

3. State Efforts to Expand Access to Contraception Necessarily Rely on Federal Action

Recognizing the economic and public health benefits of access to contraceptive care and services, the *Amici* States have taken significant steps on their own. Many States have adopted contraceptive coverage requirements under state law, expanded access under Medicaid programs, and implemented Title X programs. Several *Amici* States—California, Illinois, Maine, Maryland, Massachusetts, New York, Oregon, and Vermont—have recognized that no-cost contraception

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[9] L. Sobel et al., *The Future of Contraceptive Coverage*, The Henry J. Kaiser Family Foundation (Jan. 2017), https://www.kff.org/womens-health-policy/issue-brief/the-future-of-contraceptive-coverage/.

[10] D. Eisenberg et al., *Cost as a Barrier to Long-Acting Reversible Contraceptive (LARC) Use in Adolescents*, 52 JOURNAL OF ADOLESCENT HEALTH S59-S60 (2013).

[11] B. DiJulio et al., *Data Note: Americans' Challenges with Health Care Costs*, The Henry J. Kaiser Family Foundation (Mar. 2, 2017), https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/.

[12] L. Sobel, *The Future of Contraceptive Coverage*, *supra* n.9.

helps women plan their families, bringing about the additional benefits discussed above. These States have already enacted laws to require no-cost coverage for state-regulated plans.[13]

State initiatives, however, can only go so far. The federal Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*, preempts States from imposing coverage requirements on self-funded plans offered by employers. Such plans cover about 58% of workers with employer-sponsored insurance.[14] For this reason, the ACA's contraceptive mandate plays a critical role in ensuring access to no-cost contraception. The Rules threaten this access by allowing virtually any employer with a self-insured plan to opt-out of the mandate for a religious or moral reason without offering any explanation.

B. The Rules Will Result in More Women Seeking Contraceptive Coverage through State-Funded Sources, Further Straining Essential Programs

Defendants challenge Pennsylvania's standing by asserting that it is speculative "to assume that…gainfully employed women will meet the low-income requirements" of state-funded programs should they lose their employer-sponsored coverage for contraception. Def. Opp. at 15. However, many women who lose their employer-sponsored coverage *will* seek out contraceptive care through and qualify for state-funded programs. Millions of women across the

[13] An overview of State laws and regulations is provided by Guttmacher Institute, *Insurance Coverage of Contraceptives* (Oct. 2017), https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives. *See also* Cal. Ins. Code § 10123.196; Conn. Gen. Stat. § 38A-503e; Del. Code Ann. tit. 18, § 3559; Haw. Rev. Stat. § 432:1-604.5; 215 Ill. Comp. Stat. 5/356Z.4; Iowa Code § 514C.19; Me. Rev. Stat. tit. 24, § 2332-J, amended by Public Law, Chapter 190 (June 13, 2017); Md. Code, Ins. §§ 15-826, 15-826.1; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.M. Stat. Ann. §§ 59A-22-42; 59A-46-44; N.Y. Ins. Law §§ 3216, 3221, and 4303; N.C. Gen. Stat. § 58-3-178; Or. Rev. Stat. § 743A.066; R.I. Gen. Laws §§ 27-19-48, 27-18-57, 27-20-43; Vt. Stat. tit. 8, § 4099c; Wash. Admin. Code § 284-43-5150. State laws routinely include exemptions from mandatory coverage for prescription contraceptives for religious employers. *See, e.g.*, Conn. Gen. Stat. § 38A-503e; Del. Code Ann. tit. 18, § 3559; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017.

[14] U.S. Dept. of Health & Human Services, Medical Expenditure Panel Survey, *Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State: United States, 2016*, https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.htm ("ARHQ Database").

country, including in Pennsylvania and the *Amici* States, are eligible for a range of state-funded programs despite being gainfully employed and/or receiving coverage through an employer-sponsored plan. Moreover, the *Amici* States have found that women who cannot utilize existing health care coverage (particularly when it comes to reproductive health) routinely seek coverage from state-funded programs, including at community health centers.

Among the *Amici* States, eligibility limits for state-sponsored programs extend to 300% of the Federal Poverty Level ("FPL") (and in limited circumstances beyond), with many such programs falling in the range of 200% to 250% of FPL.[15] With the 2017 FPL set at $20,420 for a family of three, $24,600 for a family of four, and higher for larger families, *see* 82 Fed. Reg. 8,831, 8,832 (Jan. 31, 2017), this means that many women earning more than $40,000 per year and even some women earning over $70,000 may be eligible under these programs. While each State has a unique composition of programs, they generally fall into three categories: Medicaid, Medicaid Family Planning Expansion, and Title X/State Family Planning. Coverage through employer-sponsored insurance generally does not render women ineligible for these programs, particularly where coverage has been declined by the employer, though not all States serve as secondary payers under their Medicaid programs. As shown in the table below, a significant number of women *with insurance* will be income eligible for coverage under state programs when their employers choose to avail themselves of the exemptions created by the Rules. Overall, for the States included in the estimate, there are 5,035,365 income-eligible women, with

[15] Kaiser Family Foundation, *Medicaid Income Eligibility Limits for Adults as a Percent of the Federal Poverty Level*, https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D; Guttmacher Institute, *Medicaid Family Planning Eligibility Expansions*, (Oct. 2017), https://www.guttmacher.org/state-policy/explore/medicaid-family-planning-eligibility-expansions. Several States offer coverage for certain segments of the population, such as children up to the age of 19 or individuals with disabilities, that are at or exceed 300% FPL.

3,035,326 in self-funded plans.[16] In Pennsylvania, where there is no contraceptive equity law, 580,295 women are income eligible for state-funded services.

State	Insured, Income-Eligible Women Between the Ages of 15 and 45[17]	Percent of Enrollees Covered Under a Self-Funded Plan[18]	Insured, Income-Eligible Women Between Ages of 15 and 45 in Self-Funded Plans
California	1,415,247	41.6%[19]	588,743
Connecticut	151,198	59.3%	89,660
Delaware	45,491	68.3%	31,070
Dist. of Columbia	27,375	N/A	27,375
Hawaii	88,650	37.6%	33,332
Illinois	612,778	63.3%	387,888
Maryland	277,509	49.6%[20]	137,644
Massachusetts	365,762	56.6%	207,021
New York	811,392	53.9%	437,340

[16] These numbers are derived from the Interactive Public Use Microdata Series (https://usa.ipums.org/usa/) which provides detailed data from the U.S. Census Bureau's American Community Survey (2015), the State Health Access Data Assistance Center, and the Agency for Healthcare Research and Quality. Each person is assigned to a household health insurance unit ("HIU"). The incomes of all members of the same HIU are summed and divided by the FPL for the relevant household size to generate the income of the HIU as a percentage of the FPL. For Column 2, the number reflects women who: (a) are between the ages of 15 and 45; (b) have employer/union provided health insurance; and (c) have HIU income under the relevant percent of the FPL to qualify for that State's program. That initial estimate is further refined (Column 4) based on the percentage of enrollees in self-insured employer plans in each State (Column 3), provided that the State has a contraceptive equity law.

[17] For each State on the list, the following is the highest FPL for a broadly applicable program that is at least partially state funded: California—200% (Family PACT); Connecticut—263% (Medicaid Family Planning Expansion); Delaware—250% (Title X); District of Columbia—215% (Medicaid); Hawaii—250% (Title X); Maryland—250% (Title X); Massachusetts—300% (Sexual Reproductive Health Program); New York—223% (Family Benefit Program); Pennsylvania—220% (Medicaid Family Planning Expansion); Vermont—200% (Department of Health Global Commitment Investment Grant); Virginia—200% (Plan First Program); Washington—260% (Take Charge Program).

[18] The percentage of self-insured plans is taken from the ARHQ Database. *See* n.14, *supra*. All of the listed States, except the District of Columbia, Pennsylvania, and Virginia, have contraceptive equity laws that generally require state-regulated plans to cover all FDA-approved forms of contraception.

[19] Relying on a different data set for a different year, California has cited a figure of 61% of covered workers in self-insured plans in its own litigation. Among other things, the difference in these figures is attributable to the fact that, in 2016, one carrier dropped significant coverage in the self-insured market. Consistent with other efforts to keep this estimate conservative, the lower number is utilized here.

[20] A 2016 Report from the Maryland Insurance Administration concluded that 49.6% of all commercial health insurance plans in the State are self-insured. Maryland Insurance Administration, *2016 Maryland Covered Lives Report MSAR #7797* (Nov. 2016), *available at http://www.mdinsurance.state.md.us/Consumer/Appeals%20and%20Grievances%20Reports/2016-Covered-Lives-Report-MSAR7797.pdf.* The ARHQ Database (*see* n.13) provides a slightly higher number of 56.8%. Again, the lower number is utilized here.

Pennsylvania	580,295	N/A	580,295
Vermont	23,575	60.2%	14,192
Virginia	318,424	N/A	318,424
Washington	317,669	57.4%	182,342
Total	**5,035,365**		**3,035,326**

Several States will also be *required* to fund coverage for many women under the States' existing Medicaid programs. State Medicaid programs can and do serve as a secondary payer for eligible individuals even if they have other forms of insurance. Using the same criteria as with the table above, but shifting the FPL to the relevant State's basic Medicaid program income threshold (138% FPL), approximately 757,307 eligible women can be identified in Connecticut (50,498), the District of Columbia (27,375), Hawaii (16,649), Maryland (83,336), Massachusetts (110,701), Pennsylvania (376,451), and Washington (92,297) alone.

C. Defendants Are Incorrect to Assume that State-Funded Programs Can Make Up for the Loss in Employer-Sponsored Coverage

Defendants seek to minimize the impact of the Rules on both the States and women seeking coverage. In this litigation, Defendants contend that States will not be harmed or that the harm is too speculative to litigate at this juncture. *See* Def. Opp. 16. In the Rules, though, Defendants assert that women affected by the new exemptions will be able to turn to state-funded programs to obtain contraceptives. *See, e.g.*, 82 Fed. Reg. at 47,803. In seeking to have it both ways, Defendants are doubly wrong. States suffer direct, economic harm in two separate ways under these Rules. Some women will obtain replacement coverage through state-funded programs, causing a direct financial impact to the States, *see* Part I.B., *supra*. Other women will not be able to obtain replacement coverage, either because they are ineligible or because their State lacks resources to cover all women. In some of those circumstances, States will be forced to bear additional costs from unintended pregnancies. Making matters worse, Defendants have

underestimated the number of women affected by the Rules and thus also underestimated the additional strain that will be placed on the States' programs.

1. State-Funded Programs Are Inadequate Replacements for the Contraceptive Coverage Mandate

While Defendants assume that Medicaid and other state-funded programs will be able to accommodate women who lose contraceptive coverage due to the Rules, *see, e.g.*, 82 Fed. Reg. at 47,803, those programs were not designed to replace the ACA's contraceptive coverage guarantee and simply will not cover all women affected. As Defendants recognize, the ACA applies to all women regardless of income, whereas state-funded programs have eligibility requirements. As a consequence, many women who lose contraceptive coverage through their employer cannot turn to state programs at all.

Even where eligibility requirements are met, States have limited resources to meet women's needs. In Massachusetts, only 25% of the need for publicly funded contraceptive services was met by publicly supported providers in 2014. Other States face similar hurdles. In California, 2.6 million residents were in need of publicly funded contraceptive services in 2014, yet the State's family planning network was only able to meet 50% of that need. That year, New York's family planning network was able to meet only 32% of the need for publicly funded contraceptive services.[21] These facts undercut Defendants' suggestion that state-funded programs will be sufficient to prevent harm to women who lose contraceptive coverage.

[21] J.J. Frost et al., *Contraceptive Needs and Services, 2014 Update*, Guttmacher Institute, at 30 (Sept. 2016), *available at* https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

In addition, States incur billions of dollars in costs from unintended pregnancies, some of which will occur when women affected by the Rules are unable to find alternative sources of contraceptive coverage. For example, in California in 2010, 64.3% of unplanned pregnancies that went to birth were publicly funded. These pregnancies cost the State around $689.3 million. For New York, the cost per pregnancy was $25,281, with a total cost of $601.1 million in 2010. That year, Massachusetts spent $138.3 million on publicly funded unplanned pregnancies.[22]

2. Defendants Underestimate the Effects of the Rules

Defendants also underestimate the likely effect of the Rules on women nationwide. Defendants acknowledge that the Rules will result in hundreds of thousands of employees and their dependents losing access to the no-cost contraceptive coverage guaranteed by the ACA. 82 Fed. Reg. at 47,821-24. Defendants estimate that this number includes approximately 31,700 to 120,000 women of childbearing age who currently use contraception. *Id.* at 47,821, 47,823. Defendants also estimate that, for those who lose coverage, out-of-pocket costs will increase nearly $600 per woman per year, or between $18.5 and $63.8 million nationwide. *Id.* at 47,821, 47,824.

Defendants' calculations are based on assumptions designed to minimize the apparent impact of the Rules. For example, Defendants assume, based on what they acknowledge is insufficient evidence, *see* 82 Fed. Reg. at 47,816, that employers—and particularly larger employers—will make limited use of the new exemptions created by the Rules.[23] For this reason,

[22] A. Sonfield et al., *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care National and State Estimates for 2010*, Guttmacher Institute (Feb. 2015), https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf.

[23] This problem implicates both Defendants' upper- and lower-bound estimates. The upper-bound estimate is derived, in part, from calculations based on the number of employers who did not provide contraceptive coverage prior to the ACA. Defendants put this figure at 6%; however, as they acknowledge, the survey they base this figure on indicated that only 63% of employers reported providing

Defendants assert that the vast majority of the approximately 1,027,000 people they estimate were receiving contraceptive coverage through the accommodation under the prior regulations will continue to receive coverage through that accommodation, despite the availability of the new exemptions. *See* 82 Fed. Reg. at 47,820-21. Defendants also assume that no significant number of additional employers—meaning employers that did not previously qualify for an accommodation—will claim the new exemptions. *Id*.; *see also* 82 Fed. Reg. 47,838, 47,857-58 (Oct. 13, 2017).

Additionally, Defendants underestimate how many of the people who will lose coverage are women of childbearing age who use contraception. For example, Defendants assume that the percentage of people covered by employer-sponsored plans who are women of childbearing age is equal to the percentage of the general population who are women of childbearing age. 82 Fed. Reg. at 47,819, 47,821. This assumption is incorrect. According to 2015 American Community Survey data, women of childbearing age are overrepresented in the pool of people receiving employer-sponsored insurance relative to the general population (22.3% to 20.5%); this is attributable in part to the fact that most children and elderly Americans—who are by definition not women of childbearing age—are insured through Medicaid, Medicare, or other non-employer-based programs.[24]

contraceptive coverage. The remaining 37% either did not provide coverage (6%) or did not know whether their plan provided coverage (31%). *See* 82 Fed. Reg. at 47,822 n.88.

[24] *See* Kaiser Family Foundation, *Health Insurance Status: Coverage of Children 0-18*, https://www.kff.org/other/state-indicator/children-0-18/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (showing that only 49% of children received employer-sponsored insurance).

The Rules are also designed to suppress collective knowledge of their impact. They make it difficult for interested parties—including federal and state governments—to learn which employers are ending coverage by claiming either a religious or moral objection. First, the Rules do not require employers who claim the exemption to provide notice or certification to any governmental or regulatory body. *See, e.g.* 82 Fed. Reg. at 47,808-09. Second, the Rules do not require employers who claim the new exemptions to provide even employees with any special notice that they are losing coverage—the only notices required are the standard health care disclosures already required by federal law. *Id*. Employees, then, may need to read through pages of insurance plan documents to determine whether they have lost contraceptive coverage. *Id*. Ultimately, this obscurity will further harm the States, by making it more difficult to assist affected women in finding replacement coverage or free or low-cost contraception.

D. The Rules Create Legally Cognizable, Non-Economic Harm to the States

Defendants' violations of the APA and the Establishment Clause have also caused irreparable, non-economic harm to the States.

1. States Have Been Deprived of a Meaningful Opportunity to Comment on the Rules

Defendants' failure to follow the notice-and-comment rulemaking process required by the APA has substantially and irreparably harmed the States. To ensure that the general public and potentially affected parties have the opportunity to participate in and understand federal agency action and policymaking, the APA requires federal agencies engaging in substantive rulemaking to provide notice of a proposed rulemaking and an opportunity to comment. 5 U.S.C. § 553. These requirements serve critical functions: (1) ensuring that agency regulations are tested; (2) providing fairness to affected parties; and (3) giving parties an opportunity to develop the record in support of their objections, which enhances the quality of judicial review. *Council Tree*

Commc'ns, Inc. v. F.C.C., 619 F.3d 235, 250 (3d Cir. 2010). Defendants promulgated the Rules without adhering to the required notice and comment procedures. Instead, Defendants invoked the APA's "good cause" exception. For the reasons explained *infra* at 18-20, Defendants did not have good cause to evade the APA's rulemaking requirements.

Defendants' failure to adhere to the APA's rulemaking requirements denied the States the opportunity to "effective[ly] participat[e] in the rulemaking process" and to ensure that their interests were taken into consideration.[25] *See Sharon Steel Corp. v. E.P.A.*, 597 F.2d 377, 381 (3d Cir. 1979). As discussed, the regulations implemented through the Rules affect important state interests. The States had a right to raise their concerns with Defendants through the notice-and-comment process *before* the regulations went into effect—at an "early stage" of the rulemaking process when the Defendants were likely to give "real consideration to alternative ideas." *State of N.J., Dept of Envtl. Prot. Agency v. U.S. E.P.A.*, 626 F.2d 1038, 1049 (D.C. Cir. 1980) (quoting *U.S. Steel Corp. v. U.S. E.P.A.*, 595 F.2d 207, 214-15 (5th Cir. 1979)); *see also Levesque v. Block*, 723 F.2d 175, 187 (1st Cir. 1983) ("[N]otice and the opportunity for comment must come at a time when they can feasibly influence the final rule. Ordinarily this can only take place before a rule takes effect.").[26]

[25] States regularly submit comments during agency rulemaking when state interests or the interests of state residents may be affected by the resultant rules. *See, e.g.*, Multistate Comment Letter on Notice of Proposed Rulemaking to Student Assistance General Provisions (81 Fed. Reg. 39,330) (Aug. 1, 2016), *available at* https://www.regulations.gov/document?D=ED-2015-OPE-0103-9542; Multistate Comment Letter on Proposed Rule: Arbitration Agreements (81 Fed. Reg. 32,829) (Aug. 11, 2016), *available at* https://www.regulations.gov/document?D=CFPB-2016-0020-6183; Multistate Comment Letter on Proposed Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act (79 Fed. Reg. 23,142) (Aug. 8, 2014), *available at* https://www.regulations.gov/document?D=FDA-2014-N-0189-79248; Multistate Comment Letter on Proposed Rule: Hazardous Materials: Volatility of Unrefined Petroleum Products and Class 3 Materials (82 Fed. Reg. 5,499) (May 19, 2017), *available at* https://www.regulations.gov/document?D=PHMSA-2016-0077-0074.

[26] The Supreme Court's decision in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009), does not foreclose the States' argument. In *Summers*, the Court explained that "deprivation of a procedural right *without some concrete interest that is affected by the deprivation*—a procedural right *in vacuo*—is

Providing the States a late, post-implementation opportunity to comment on the Rules "cannot substitute" for proper notice-and-comment rulemaking. *Sharon Steel Corp*., 597 F.2d at 381; *see also Wagner Elec. Corp. v. Volpe,* 466 F.2d 1013, 1020 (3d Cir. 1972) ("[T]he Administrative Procedure Act requires notice *before* rulemaking, not after."). After all, "[i]f a period for comments after issuance of a rule could cure a violation of the APA's requirements, an agency could negate at will the Congressional decision that notice and an opportunity for comment must precede promulgation." *Sharon Steel Corp.*, 597 F.2d at 381.

There is no reasonable possibility that Defendants will give meaningful consideration to the States' objections to the Rules now that the Rules have already gone into effect. As a general matter, it is particularly unlikely that an agency will consider after-the-fact comments to promulgated regulations where, as here, the regulations are "complex and far-reaching" and would be burdensome to unwind. *Northern Mariana Islands v. U.S.*, 686 F. Supp. 2d 7, 17-18 (D.D.C. 2009); *see also U.S. Steel Corp.*, 595 F.2d at 214-15 ("We doubt that . . . the Secretary would seriously consider [] suggestions after the regulations are a Fait accompli." (quotation marks and citations omitted)). Defendants' actions bear out this concern. The regulations were drafted to respond to issues raised by employers in a number of pending cases, and Defendants wasted no time before seeking to resolve those cases on the basis of the Rules. On the *first business day* after the Rules were published in the Federal Register, Defendants agreed to dismiss the pending cases. *See, e.g.*, Joint Motion by the Parties to Withdraw Case, *David Zubik, et al. v. Burwell et al.*, Nos. 14-1376 & 14-1377 (3d Cir. Oct 16, 2017); Joint Stipulation of Dismissal of Appeal, *Roman Catholic Archbishop, et al. v. Burwell et al.*, Nos. 13-5371 & 14-

insufficient to create Article III standing. *Id.* at 496 (emphasis added). Here, the States have specific and concrete interests affected by the Rules, including the health and well-being of women and children as well as the expenditure of state funds on contraceptive coverage and unintended pregnancies.

5021 (D.C. Cir. Oct. 16, 2017). Many of these cases have already been dismissed on the basis of Defendants' motions and stipulations of dismissal. Defendants have thus already demonstrated their complete commitment to these "interim" Rules.[27]

Depriving the States of their right to participate in and influence the regulatory process, thereby undermining their ability to protect their interests and those of their residents, constitutes a significant and irreparable harm to the States. *See Northern Mariana Islands,* 686 F. Supp. 2d at 17-18 (holding that an agency's failure to follow the notice-and-comment process under the APA constituted irreparable harm); *Conservation Law Foundation, Inc. v. Busey*, 79 F.3d 1250, 1271 (1st Cir. 1996) (explaining that agencies' failure to follow rulemaking procedures constitutes irreparable harm where the agencies' actions cause them to "become entrenched in a decision…because they have made commitments or taken action to implement the…decision"). There is no adequate remedy for the harm caused by Defendants' actions other than injunctive relief. *See Northern Mariana Islands,* 686 F. Supp. 2d at 17-19 (granting a preliminary injunction where an agency failed to follow the notice-and-comment process under the APA).

2. The Establishment Clause Violation Creates Irreparable Harm

In addition, Defendants' violation of the Establishment Clause has inflicted a constitutional injury that constitutes "per se irreparable harm for the purpose of granting a preliminary injunction." *McCormick v. Hirsch*, 460 F. Supp. 1337, 1349 (M.D. Pa. 1978); *see also Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 303 (D.C. Cir. 2006); *Ingebretsen v. Jackson Pub. Sch. Dist*., 88 F.3d 274, 280 (5th Cir. 1996); *Parents' Ass'n of P.S. 16 v. Quinones*, 803 F.2d 1235, 1242 (2d Cir. 1986); *ACLU of Ill. v. City of St. Charles*, 794 F.2d

[27] In light of these actions already taken by Defendants in reliance of the Rules, their argument that any error was "harmless" rings hollow. *See* Def. Opp. at 28-29.

265, 274 (7th Cir. 1986). The injury caused by violations of the Establishment Clause is both immediate—it "occurs the moment the government action takes place"—and without adequate remedy at law. *Chaplaincy of Full Gospel Churches*, 454 F.3d at 303. As such, "where a movant alleges a violation of the Establishment Clause, this is sufficient, without more, to satisfy the irreparable harm prong for the purposes of the preliminary injunction determination." *Id*.; *see also Mullin v. Sussex County, Del.*, 861 F. Supp. 2d 411, 427 (D. Del. 2012).

II. THE RULES ARE UNLAWFUL AND UNCONSTITUTIONAL

Defendants have produced unlawful Rules through an unlawful process. They have no legal justification for their failure to engage in notice and comment rulemaking. In addition, the Rules themselves are arbitrary and capricious, contrary to the ACA, and unconstitutional. For all of these reasons, the APA requires that the Rules be set aside. 5 U.S.C. § 706(2)(A)-(D).

A. Defendants Do Not Have a Legal Justification for Issuing Interim Final Rules

The APA permits agencies to dispense with notice and comment rulemaking only for "good cause"—when doing so would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); *Jifry v. Fed. Aviation Admin.*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (the good cause exception "excuses notice and comment in emergency situations, or where delay could result in serious harm"). Defendants incorrectly contend that the "public interest" and "impracticable" prongs of the exception justify their failure to follow notice and comment procedures. *See* 82 Fed. Reg. at 47,814-15; 82 Fed. Reg. at 47,855.[28]

[28] Neither the Internal Revenue Code, nor ERISA, nor the Public Health Services Act authorize Defendants to promulgate the Rules as interim final regulations. The statutory provisions identified by Defendants contain general grants of rulemaking authority and do not authorize them to violate the APA. *See Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18-19 (D.D.C. 2010); *see also* 5 U.S.C. § 559 (a "subsequent statute may not be held to supersede or modify [§ 553]…except to the extent that it does so expressly").

Generally, "any time one can expect real interest from the public in the content of the proposed regulation, notice-and-comment rulemaking will not be contrary to the public interest." *Levesque*, 723 F.2d at 185. However, the public interest prong may "appropriately [be] invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the [rules] …." *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 95 (D.C. Cir. 2012) (internal quotations omitted). Here, Defendants cannot plausibly claim that the Rules are of no public interest, or that dispensing with notice and comment procedures was necessary "to prevent the [Rules] from being evaded." *Util. Solid Waste Activities Grp v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001).

The second prong—the impracticability ground—may only be invoked when "the agency [can]not both follow [notice and comment rulemaking] and execute its statutory duties." *Levesque*, 723 F.2d at 184. Defendants do not even attempt to meet this standard. They contend only that notice and comment rulemaking would have been complicated by ongoing litigation. 82 Fed. Reg. at 47,814, 47,855.[29] Nothing about that ongoing litigation "unavoidably prevented" the agencies from complying with the APA. *Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980).

Defendants also seek to justify their issuance of interim final regulations by citing the "more than 100,000 public comments" on earlier versions of the regulations. 82 Fed. Reg. at 47,814; 82 Fed. Reg. at 47,855. There is no basis in the APA's good cause exception for disregarding notice and comment on a regulation because an agency has already accepted comments on prior versions of the regulation. But even if there were, the comments that Defendants previously received were particular to the regulatory actions taken at the time—most

[29] Defendants' reliance on *Priests for Life v. U.S. Dept. of H.H.S.*, 772 F.3d 229, 276–77 (D.C. Cir. 2014), which upheld their promulgation of interim final regulations following remand in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014), is misplaced. *Priests for Life* concluded that the interim final regulations at issue were "minor, meant only to 'augment current regulations in light of'" *Wheaton College*. 772 F.3d at 276 (quoting 79 Fed. Reg. 51,092 (Aug. 27, 2014)). The Rules are not minor or meant to augment current regulations.

notably, the creation of an accommodation for religious nonprofits and closely held for-profit corporations. The Rules represent a stark departure from that prior effort.

B. The Rules Exceed Defendants' Authority Under The ACA

There is no statutory authority for the new exemptions created by the Rules. The ACA itself does not authorize any such exemptions. In the absence of such authorization, Defendants are prohibited from ignoring the ACA's mandate to provide cost-free contraceptive coverage unless some other statutory provision unambiguously requires such an exemption. The principal statute that Defendants cite, the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §§ 2000bb *et seq.*, provides no support for the sweeping religious and moral exemptions.

1. The Rules Are Not Authorized by the ACA

The text, structure, and legislative history of the ACA make clear that the statute does not provide Defendants with authority to create the broad new exemptions set forth in the Rules. The ACA delegates to Defendants—through the Health Resources and Services Administration (HRSA), an agency within HHS—discretion to determine *which* preventive services for women shall be covered by the Act, not *who* shall be required to provide coverage.

The ACA requires that regulated group health plans "s*hall* … provide coverage for and *shall not* impose any cost sharing requirements for" preventive care and screenings for women. 42 U.S.C. § 300gg–13(a)(4). "Shall" is a mandatory term that "normally creates an obligation impervious to judicial [or agency] discretion." *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Further, the ACA provides only one exemption to the preventive services requirement: for "grandfathered health plans." 42 U.S.C. § 18011(e). The fact that Congress included one specific exemption indicates that it did not intend to delegate authority to create additional exemptions. *See Sierra Club v. E.P.A.*, 705 F.3d 458, 467 (D.C. Cir. 2013).

The language of § 2713(a)(4) makes clear that HRSA's charge is limited to identifying the types of preventative care services to be covered. Critically, this section delegates authority to HRSA to develop guidelines setting forth "*additional* preventive care and screenings" to be covered for women. 42 U.S.C. § 300gg-13(a)(4) (emphasis added). Congress's selection of HRSA as the agency with authority to develop these guidelines aligns with the agency's narrow charge. HRSA has expertise in improving access to health care services for women; it has no expertise in crafting religious and moral objections to contraception.

Section 2713(a)(4) directs HRSA to develop its guidelines "for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). That textual command makes plain that, in developing the guidelines, HRSA must honor the purpose of the Women's Health Amendment: to ensure that "all health plans cover comprehensive women's preventive care and screenings…at little or no cost to women." 155 Cong. Rec. S12025 (Dec. 1, 2009) (Sen. Boxer).[30] Notably, in 2012 the Senate rejected an attempt to add to the ACA a "conscience amendment," which would have authorized employers and insurers to deny coverage based on their "religious beliefs or moral convictions." 158 Cong. Rec. S539 (Feb. 9, 2012) (S. Amdt. 1520, Section (b)(1), 112th Congress (2011-2012)).

2. Defendants' Justifications for the Rules Are Meritless

Defendants do not have authority under the ACA to create the new exemptions contained in the Rules. While Defendants assert otherwise, the Rules do not point to any text or ambiguity in the Act. Instead, Defendants maintain that they may issue the Rules because Congress did not

[30] While the Amendment did not specify which preventive services would be covered, Congress expected that contraception and family planning counseling would be included. *See, e.g.*, 155 Cong. Rec. S12028 (Dec. 1, 2009) (Sen. Mikulski) (stating that the Amendment "provides family planning"); 155 Cong. Rec. S12671 (Dec. 8, 2009) (Sen. Durbin) ("millions more women will have access to affordable birth control and other contraceptive services").

"prohibi[t] them from providing conscience protections." 82 Fed. Reg. at 47,844. But courts "will not presume a delegation of power based solely on the fact that there is not an express withholding of such power." *Michigan v. E.P.A.*, 268 F.3d 1075, 1082 (D.C. Cir. 2001) (internal quotations omitted). Defendants also note that "many Federal healthcare laws and regulations provide exemptions for objections based on religious beliefs" and moral convictions. 82 Fed. Reg. at 47,809; 82 Fed. Reg. at 47,844-45 & n.1. The ACA does not provide such broad exemptions.[31]

Defendants contend that the contraceptive mandate "imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have [religious and] moral convictions opposed to providing contraception coverage." 82 Fed. Reg. at 47848. This argument runs up against the settled rule that "there exists no general administrative power to create exemptions to statutory requirements based upon the agency's perception of costs and benefits." *Public Citizen v. F.T.C.*, 869 F.2d 1541, 1556 (D.C. Cir. 1989) (internal quotations omitted).

Defendants next claim that, because they have "repeatedly exercised their discretion to create and modify various exemptions," they must have authority to do so. 82 Fed. Reg. 47,809; *see also* 82 Fed. Reg. at 47,840. Not so. Before these Rules, Defendants only exempted houses of worship from the contraceptive mandate.[32] The basis for that exemption is RFRA, not the ACA

[31] The ACA does contain anti-discrimination protections for those who have a religious objection to participating in aid-in-dying procedures. 42 U.S.C. § 18113.

[32] This original exemption ("Church Exemption") is clearly distinguishable from the broader exemptions created by the Rules. The Church Exemption is consistent with RFRA, the principle of non-interference enshrined in the First Amendment, and similar exemptions provided in various state contraceptive coverage laws. Churches are different from other employers. *See* 80 Fed. Reg. 41,318, 41,325 (July 14, 2015); *Real Alternatives, Inc. v. Sec'y Dept. of H.H.S.*, 867 F.3d 338, 350–53 (3d Cir. 2017) (noting that "respecting church autonomy" is protected both by federal law and the First Amendment). As Defendants have explained, the Church Exemption was created to respect the "particular sphere of autonomy" that protects churches from government interference. 80 Fed. Reg. at 41,325.

itself. *See* 77 Fed. Reg. 8,725, 8,729 (Feb. 15, 2012) (Final Rules); *see also* 76 Fed. Reg. 46,621, 46,623-24 (Aug. 3, 2011) (Interim Final Rules) (explaining that Defendants' authority "to establish an exemption applies only to group health plans sponsored by religious employers").

Defendants also suggest that the exemptions are justified by RFRA, but RFRA does not give Defendants unfettered discretion to grant exemptions to the contraceptive mandate. Agencies must harmonize federal statutes in order to honor Congress's intent, *see Boston & Maine Corp. v. Mass. Bay Transp. Auth.*, 587 F.3d 89, 99 n.1 (1st Cir. 2009), so the ACA's mandate can only be limited to the extent required by RFRA. The accommodation already satisfies the federal government's obligations under RFRA. It ensures that employees continue to receive the coverage required by the ACA without imposing a substantial burden on objecting employers' religious exercise. *See, e.g.*, *Real Alternatives*, 867 F.3d at 356 n.18 (approving the analysis of the accommodation in *Geneva College v. Sec'y Dept. of H.H.S.*, 778 F.3d 422, 427 (3d Cir. 2015)). RFRA requires nothing more. Moreover, RFRA plainly cannot justify the Moral Exemption Rule. *See Real Alternatives*, 867 F.3d at 349-350.

In sum, the new exemptions created by the Rules are contrary to law because they excuse compliance with a statutory requirement so long as there is any claimed religious burden, rather than a substantial burden as required by RFRA. The Religious Exemption Rule—which applies to a broad range of employers, rather than the narrower class of churches, religious nonprofits, and closely held for-profit corporations that the Supreme Court has squarely concluded are protected by RFRA—excuses all objecting employers from undertaking any steps, however minimal, to ensure that their employees retain access to statutorily guaranteed contraceptive coverage; and in doing so, it frustrates the government's compelling interest in ensuring that

women have access to cost-free contraception.[33]

C. The Rules Are Arbitrary and Capricious Because They Constitute a Change of Policy for which Defendants Did Not Provide a Satisfactory Explanation

Defendants also violated the APA by promulgating rules that constitute a reversal of their previous policies without providing an adequate explanation for this reversal. To satisfy the APA, an agency engaging in rulemaking "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). In particular, an agency reversing or departing from a previous policy "is obligated to supply a reasoned analysis for the change." *Id.* at 42; *see also Encino Motorcars, LLC v. Navaro*, 136 S. Ct. 2117, 2126 (2016) (explaining that "[an] agency must at least display awareness that it is changing position and show that there are good reasons for the new policy" (quotation marks omitted)). An agency's failure to provide a reasoned analysis for its change of position renders the action arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 48-51.

The requirement that an agency justify its change of position not only ensures that there are "good reasons" for the agency's new policy but also guarantees that agencies will consider any reliance interests engendered by the policies. *F.C.C. v. Fox Tel. Stations, Inc.*, 556 U.S. 502,

[33] Not only are the Rules not required by RFRA, but they also run afoul of Title VII, as amended by the Pregnancy Discrimination Act, which makes clear that discrimination "on the basis of pregnancy, childbirth, or related medical conditions" is unlawful discrimination on the basis of sex. 42 U.S.C. §§ 2000e-2(a), (k); Equal Employment Opportunity Comm'n, Decision (Dec. 14, 2010), https://www.eeoc.gov/policy/docs/decision-contraception.html ("failing to offer insurance coverage for the cost of prescription contraceptive drugs and devices" for women constitutes unlawful discrimination). In addition, the Rules violate the non-discrimination provision of the ACA, which prohibits discrimination on the basis of sex. *See* 42 U.S.C. § 18116.

515 (2009). An agency must provide an even "more detailed justification" when the agency's "previous policy engendered serious reliance interests that must be taken into account." *Id.* An agency's failure to consider such reliance renders the action arbitrary and capricious. *Id*. at 516.

The Rules are not simply a reversal of position. They are an about-face from a conclusion reached after the commissioning of a study of the matter and extensive notice-and-comment procedures. In addition, Defendants asserted positions that directly conflict with the Rules to the Supreme Court on two occasions, and a majority of the Supreme Court (Justice Kennedy in concurrence and the dissenting opinions in *Hobby Lobby*) agreed that the government has a compelling interest in ensuring access to contraception—an interest Defendants now disclaim. These facts make the lack of support for the reversal particularly egregious.

In the absence of new facts, Defendants fail to provide any other support for changing their approach. While the Rules reference *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014) and *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), these decisions do not support Defendants' new policies, as neither decision stands for the proposition that such broad exemptions or accommodations are required. To the contrary, the *Zubik* Court specifically instructed that: "the parties on remand should be afforded an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive *full and equal health coverage, including contraceptive coverage*." 136 S. Ct. at 1560 (emphasis added). The Rules are both inconsistent with Defendants' previous policies and with the Supreme Court's instructions.

In particular, the Rules are premised on a significant weakening of Defendants' prior view that there is a compelling government interest in ensuring women's access to contraceptive coverage. *See* 82 Fed. Reg. at 47,800; 82 Fed. Reg. at 47,848. Despite adopting new policies

based on a "reassessment of the relevant interests," the Rules fail to put forward a satisfactory explanation demonstrating that there are good reasons for this "reassessment" and policy reversal. 82 Fed. Reg. 47,800. For instance, Defendants attempt to justify their change of position by claiming that Congress did not explicitly mandate that contraception be covered under the ACA. *Id.* at 47,800-01. This statement has no bearing whatsoever on Defendants' decision to deviate from *their own* previous assessment regarding the importance of ensuring women's access to contraceptives. Moreover, Defendants' statement is misleading. Congress required coverage of "such additional preventative care and screenings" for women "provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a)(4). These guidelines *specifically* include no-cost "contraceptive methods" and "counseling" as covered preventative care for women.[34]

While Defendants are permitted to reverse their policies, they cannot do so without adhering to the requirements of the APA. Namely, they cannot engage in such an extensive reversal without providing a "reasoned analysis" showing that there are "good reasons" for the new policy and taking into account the "serious reliance interests" engendered by Defendants' previous policies. *Fox Tel. Stations*, 556 U.S. at 514-15. Defendants' failure to adequately explain their policy reversals and their wholly inadequate discussion of women's health needs and reliance interests cannot satisfy the requirements of the APA.

D. The Rules Violate the First and Fifth Amendments to the Constitution

Finally, the Rules are also unconstitutional. The Religious Exemption Rule violates the Establishment Clause because it has the primary purpose and effect of advancing the religious

[34] Health Resources & Services Administration, *Women's Preventive Service Guidelines* (2011), *available at* https://www.hrsa.gov/womens-guidelines/index.html#2.

interests of employers over the interests and autonomy of employees. *See Lemon v. Kurtzman*, 403 U.S. 602, 612-613 (1971). By singling out women for unfavorable treatment, Defendants have violated the equal protection guarantee implicit in the Fifth Amendment. *See Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1686 n.1 (2017) (equal protection claims under the Fifth and Fourteenth Amendments treated identically).

1. The Religious Exemption Rule Violates the Establishment Clause

By using their rulemaking authority to empower employers with religious objections to contraception to deny employees access to statutorily mandated contraceptive coverage, Defendants have unconstitutionally endorsed those religious objections. *See Lynch v. Donnelly*, 465 U.S. 668, 691-92 (1984) (O'Connor, J. concurring) (government action that "intentionally or unintentionally" has the effect of "convey[ing] a message of endorsement…of religion" violates the Establishment Clause); *see also Corp of Presiding Bishops v. Amos*, 483 U.S. 327, 343 (1987) (Brennan, J. concurring) (creating exemptions for for-profit businesses risks "furthering religion in violation of the Establishment Clause"). Defendants were not required by the Free Exercise Clause to create the new exemptions in the Rules, *see Employment Division v. Smith*, 494 U.S. 872, 878 (1990), and their decision to do so voluntarily is particularly problematic given the existence of the accommodation. As discussed, the accommodation relieves objecting employers of their obligation to comply with the ACA's contraceptive mandate and sets up a separate system to independently provide coverage to employees and their dependents. *See, e.g.*, *Real Alternatives*, 867 F.3d at 342. Through the Rules, Defendants have effectively granted employers a "religious veto" over access to coverage through this separate system. *Id.* at 363. In so doing, Defendants have denied women a vital statutory right and compelled employees (and insurers and the government) to conform their independent activities to the religious beliefs of

employers. *See Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995) (laws that compel employers to "conform their business practices to the particular religious practices of . . . employees" violate the Establishment Clause); *see also Hobby Lobby*, 134 S. Ct. at 2786-87 (Kennedy, J., concurring) (exercise of religion may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling").

Defendants' endorsement of religious objections to contraception comes at "the detriment of those who do not share [them]." *Estate of Thornton*, 472 U.S. at 711 (O'Connor, J., concurring). Exemptions that impose significant burdens on third parties in order to permit "others to act according to their religious beliefs" advance religious interests in violation of the Establishment Clause.[35] *See Texas Monthly v. Bullock*, 489 U.S. 1, 14–15, 18 n.8 (1989); *see also Board of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 722 (1994) (Kennedy, J., concurring) ("A religious accommodation demands careful scrutiny to ensure that it does not so burden non-adherents . . . as to become an establishment."). Here, Defendants acknowledge that the Religious Exemption Rule will deprive tens of thousands of women of contraceptive coverage, force them to seek medically necessary care from sources other than their normal health care providers, and impose tens of millions of dollars in out-of-pocket costs annually. These logistical, administrative, and financial burdens will "block many women from obtaining needed care at all." *Hobby Lobby*, 134 S. Ct. at 2788 (Ginsburg, J., dissenting). Creating this harmful religious veto is a clear Establishment Clause violation.

[35] Exemptions that "impose substantial burdens on non-beneficiaries" may be justified as necessary to "remove a demonstrated and possibly grave imposition on religious activity sheltered by the Free Exercise Clause." *Texas Monthly*, 489 U.S. at 18 n.8; *Amos*, 483 U.S. at 335-36 (religious exemption from Title VII permitted under the Establishment Clause because it was necessary to lift a "significant burden" on free exercise activity). Because of the accommodation, no such "grave imposition on religious activity" is at issue here. *Texas Monthly*, 489 U.S. at 18 n.8; *see also Real Alternatives*, 867 F.3d at 356 n.18.

2. The Rules Violate the Equal Protection Guarantee in the Fifth Amendment

Laws and regulations, like the Rules, that distribute benefits or burdens unequally on the basis of gender are presumptively unconstitutional and subject to heightened scrutiny. *See Morales-Santana*, 137 S. Ct. at 1700-01 (subjecting a "gender-based distinction infecting [immigration law]" to heightened scrutiny); *Orr v. Orr*, 440 U.S. 268, 283 (1979) ("Legislative classifications that distribute benefits and burdens on the basis of gender . . . must be carefully tailored."). The Rules insert gender-based exemptions into the preventive care requirement of the ACA. Although contraception is hardly the only "sensitive" medical service covered by the ACA, *see Real Alternatives*, 867 F.3d at 364, Defendants have elected to create exemptions applicable only to "women's preventive care" under Section 2713(a)(4). That provision was inserted into the ACA to ensure that women receive full and equal access to preventive medical care. By creating an exemption specific to this provision, the Rules undermine a statutory benefit "necessary to protect the health of female employees," while leaving coverage for male employees untouched. *See Hobby Lobby*, 134 S. Ct. at 2785-86 (Kennedy, J., concurring).

The Rules do not provide the type of "exceedingly persuasive justification" necessary to survive heightened scrutiny. *See Morales-Santana*, 137 S. Ct. at 1690; *U.S. v. Virginia*, 518 U.S. 515, 533 (1996) (the justification for a gender-based distinction must be "genuine, not hypothesized or invented post hoc in response to litigation"). Contrary to Defendants' claims, the Rules are not supported by a general governmental interest in accommodating moral and religious objections to "sensitive" medical procedures and services. *See* 82 Fed. Reg. at 47,838-39. Even assuming there were such an interest, the Rules are fatally under-inclusive. Such an interest should give rise to a broad, gender-neutral exemption rather than a gender-specific exemption for "women's preventive care." *See Orr*, 440 U.S. at 282-83 (a gender-based

distinction is unconstitutional if the proffered state interest would be "as well served by a gender-neutral classification"). Moreover, Congress did not intend for women's access to necessary medical care to be dependent upon the religious or moral beliefs of their employers; Congress declined to include such an exemption in the ACA. Defendants' legitimate interest in accommodating moral and religious objections to the ACA is limited to what is required by the Free Exercise Clause and RFRA—as discussed, the exemptions are not required by either.

Finally, Defendants' claim that the Rules are necessary to end litigation over the contraceptive mandate is misguided. An agency's "desire to resolve…pending litigation and prevent future litigation," 82 Fed. Reg. at 47,799, is not a sufficiently important interest to satisfy heightened scrutiny. *See Shaw v. Hunt*, 517 U.S. 899, 908 n.4 (1996). Moreover, Defendants' interest in avoiding litigation "rings hollow," given that the Rules have predictably led to additional litigation. *See Cotter v. City of Boston*, 323 F.3d 160, 172 n.10 (1st Cir. 2003).

CONCLUSION

For the reasons described above as well as the reasons stated in the Commonwealth of Pennsylvania's memorandum of law, the motion for a preliminary injunction should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Jonathan B. Miller, hereby certify that a true copy of the above document, filed through the CM/ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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